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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,876	12/10/2007	Terence Harden	801948-0005	3876
27910 7590 10/14/2010 STINSON MORRISON HECKER LLP ATTN: PATENT GROUP 1201 WALNUT STREET, SUITE 2800 KANSAS CITY, MO 64106-2150			EXAMINER MARX, IRENE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 10/14/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,876	Applicant(s) HARDEN ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2,3 and 5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/27/06</u> . | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1651

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 5 are vague, indefinite and confusion in that "is about the same as" is ambiguous and open to interpretation as to the degree of sameness required. Is it 99.99%, 90%, 60%, etc.?

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *Bacillus*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It does not appear that a deposit was made in this application that meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

Art Unit: 1651

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Art Unit: 1651

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a *Bacillus* strain, the sole property as claimed therefor being that it has at least 70% DNA-DNA similarity to the genome of a *Bacillus* according to Accession No. NM03/36700 and a melting temperature that is about the same as the melting temperature of a genome of this *Bacillus* strain. In contrast, the specification only provides guidance for the specific *Bacillus* strain indicated as having "Accession No. NM03/36700" without a clear indication as to the depository used..

No guidance is presented regarding the structure/function relationship between the at least 70% DNA-DNA similarity to the genome of a *Bacillus* according to Accession No. NM03/36700 and a melting temperature that is about the same as the melting temperature of a genome of this *Bacillus* strain and any specific properties of the strain(s) as claimed, such as capability of suppressing the growth of a fungus, for example. The disclosed strain is not representative of the genus of *Bacillus* strain, the sole property as claimed therefor being that it has at least 70% DNA-DNA similarity to the genome of a *Bacillus* according to Accession No. NM03/36700 and a melting temperature that is about the same as the melting temperature of a genome of this *Bacillus* strain because there is no known correlation between comprising *Bacillus* strain, the sole property as claimed therefor being that it has at least 70% DNA-DNA similarity to the genome of a *Bacillus* according to Accession No. NM03/36700 and a melting temperature that is about the same as the melting temperature of a genome of this *Bacillus* strain. and the function of the claimed invention that one of skill in the art would recognize.

Thus it is not apparent that the disclosure provided is reasonably predictive of the activity and properties of *Bacillus* strain, the sole property as claimed therefor being that it has at

Art Unit: 1651

least 70% DNA-DNA similarity to the genome of a *Bacillus* according to Accession No. NM03/36700 and a melting temperature that is about the same as the melting temperature of a genome of this *Bacillus* strain. No guidance is presented regarding the evaluation of *Bacillus* strains that have at least 70% DNA-DNA similarity to the genome of a *Bacillus* according to Accession No. NM03/36700 and a melting temperature that is about the same as the melting temperature of a genome of this *Bacillus* strain and fungal growth suppression.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention. The written description requirement is in place to ensure that "when a patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function." *Ariad Pharms. Co. v. Eli Lilly & Co.*, 94 U.S.P.Q.2d 1161, 1172 (Fed. Cir. 2010).

Therefore *Bacillus* NM03/36700 is the only isolated strain in possession of applicants if this is, indeed, the strain designation for this particular isolate..

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1651

Claims 2, 3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Korean patent 1999-079916

The claims are directed to a *Bacillus* strain(s) which has at least 70% DNA-DNA similarity to *Bacillus* NM03/36700 and has about the same genome melting temperature

The cited reference discloses a *Bacillus subtilis* strain A405 producing an antibiotic peptide having control activity of plant diseases and methods for control of such diseases using this strain, which appears to be identical to the presently claimed strain(s) (see, e.g., Title). The referenced microorganism appears to be identical to the presently claimed strain(s) and is considered to anticipate the claimed microorganism(s) since it appears to have at least 70% DNA-DNA similarity to *Bacillus* NM03/36700, has about the same genome melting temperature and has antifungal properties. Consequently, the claimed strain(s) appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 2, 3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Majewski *et al.* (Genetics **153**: 1525--1533 (December 1999)).

The claims are directed to a *Bacillus* strain(s) which has at least 70% DNA-DNA similarity to *Bacillus* NM03/36700 and has about the same genome melting temperature

The cited reference discloses a *Bacillus* strain ATCC 23350 which appears to be identical to the presently claimed strain(s) (see, e.g., instant Specification, [0085] and Table 1). The referenced microorganism appears to be identical to the presently claimed strain(s) and is

Art Unit: 1651

considered to anticipate the claimed microorganism(s) since it appears to have at least 70% DNA-DNA similarity to *Bacillus* NM03/36700, has about the same genome melting temperature and is presumed to have at least some antifungal properties. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism(s) is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 2, 3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nagao *et al.* (Novel macrolactins as antibiotic lactones from a marine bacterium, J. Antibiot. 54 (4), 333-339 (2001)

The claims are directed to a *Bacillus* strain(s) which has at least 70% DNA-DNA similarity to *Bacillus* NM03/36700 and has about the same genome melting temperature

The cited reference discloses a *Bacillus* strain which appears to be identical to the presently claimed strain(s) (see, e.g., Abstract). The referenced microorganism appears to be identical to the presently claimed strain(s) and is considered to anticipate the claimed microorganism(s) since it appears to have at least 70% DNA-DNA similarity to *Bacillus* NM03/36700, has about the same genome melting temperature and is presumed to have at least some antifungal properties. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism(s) is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed

Art Unit: 1651

microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 2, 3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Araki *et al.* (WO 9928441).

The claims are directed to a *Bacillus* strain(s) which has at least 70% DNA-DNA similarity to *Bacillus* NM03/36700 and has about the same genome melting temperature

The cited reference discloses a *Bacillus* strain which appears to be identical to the presently claimed strain(s) (see, e.g., Abstract). The referenced microorganism appears to be identical to the presently claimed strain(s) and is considered to anticipate the claimed microorganism(s) since it appears to have at least 70% DNA-DNA similarity to *Bacillus* NM03/36700, has about the same genome melting temperature and is presumed to have at least some antifungal properties. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism(s) is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 2, 3 and 5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arima *et al.* (U.S. Patent No. 3,687,926)

The claims are directed to a *Bacillus* strain(s) which has at least 70% DNA-DNA similarity to *Bacillus* NM03/36700 and has about the same genome melting temperature

Art Unit: 1651

The cited reference discloses a *Bacillus* strain ATCC 21331 which appears to be identical to the presently claimed strain(s) (see, e.g., instant Specification, [0085] and col. 1, line 43). The referenced microorganism appears to be identical to the presently claimed strain(s) and is considered to anticipate the claimed microorganism(s) since it appears to have at least 70% DNA-DNA similarity to *Bacillus* NM03/36700, has about the same genome melting temperature and is presumed to have at least some antifungal properties. Consequently, the claimed strain appears to be anticipated by the reference.

In the alternative, even if the claimed microorganism(s) is not identical to the referenced microorganism with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microorganism is likely to inherently possess the same characteristics of the claimed microorganism particularly in view of the similar characteristics which they have been shown to share. Thus the claimed strain would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651

Application/Control Number: 10/564,876

Page 10

Art Unit: 1651